REMARKS

This Application has been carefully reviewed in light of the Office Action mailed July 13, 2007, and Supplemental Office Action mailed August 9, 2007. At the time of the Office Action, Claims 1-15 were pending in this Application. Claims 1-15 were rejected. Claims 1, 6, and 11 have been amended to further define various features of Applicants' invention. Applicants respectfully request reconsideration and favorable action in this case. New Claims 16 and 17 have been added to better define various features of Applicant's invention.

Applicants appreciate the Examiner preparing the Supplemental Office Action.

Double Patenting Rejection

The Examiner provisionally rejected Claims 1-15 based on the judicially created double patenting doctrine over Claims 4-8, 12-16, 24-28, 30 and 31 of related U.S. Patent No. 6,730,266 (hereinafter '266 patent) stating that the subject matter claimed in the instant application is fully disclosed in the referenced patent.

Applicants respectfully traverse the rejection. However, to reduce the cost and time required to obtain patent protection, a Terminal Disclaimer filed in compliance with 37 C.F.R. 1.321 is attached hereto. The Terminal Disclaimer is offered in the event the Examiner converts the provisional rejection to a rejection based on non-statutory double patenting grounds. The '266 patent and the instant patent application are commonly owned by Immunocept, L.L.C.

Definitions

The following definitions from page 25 lines 11-19 of the Specifications are helpful in understanding the scope of Applicants' invention as defined in Amended Claims 1, 6 and 11 and differences between Applicants' claimed invention and various references cited by the Examiner.

> The term "hemofiltration" refers to a process of filtering blood by a membrane with separation of all formed elements, all proteins larger than effective pore size of the membrane, and retained plasma water and solute (these return to the patient) from ultrafiltrate.

The term "ultrafiltrate" refers to the filtered plasma water and solute and molecules (including target peptides and proteins containing IM) smaller than effective pore size of the membrane.

The Specification further states on page 14 lines 13-23, "[T]he hemofilter receives a stream of blood removed from the mammal and removes ultrafiltrate from the stream of blood from the mammal and thereby creates a stream of filtered blood, which is eventually returned to the mammal, and a stream of ultrafiltrate. The hemofilter sieves the ultrafiltrate, the ultrafiltrate comprised of a fraction of plasma water, electrolytes, and peptides and small proteins. The sieved blood peptides and proteins have a molecular size smaller than the pore size of the membrane; IM are included in this group."

Rejections under 35 U.S.C. § 102

Claims 1, 2 and 5 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by European Patent Application No. 0787500A1 by Mary Lou Wratten et al. ("Wratten"). Applicants respectfully traverse and submit the cited art does not teach all of the elements of the claimed embodiment of the invention.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "the identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Applicants respectfully submit that the art cited as anticipatory by the Examiner cannot anticipate the rejected Claims, because the cited art does not show all the elements of the present Claims.

Applicants respectfully note that Wratten shows a test circuit implementing a device in accordance with the invention of Wratten and used for testing the method of Wratten. See Wratten page 3, lines 6-8. Figure 1 of Wratten shows reservoir 4 with a predetermined quantity of blood for treatment. Circulating pump 2 is used to supply blood from reservoir 4 to filter 5. A filtering means defined by a semipermeable membrane filters the bloodstream by convection to form a stream of ultrafiltrate/plasma filtrate inside secondary circuit 8. See Wratten page 2 line 57 through page 3 line 3. The ultrafiltrate/plasma filtrate flows through circuit 8 and through filters 11 and 12 before returning to reservoir 4. Filter 5 also produces a

stream of eluate issuing from filter 5 through discharge tube 9 to form a stream of purified blood which may be fed back using known means into the patient's body. For test purposes as shown in Figure 1, circuit 8 and tube 9 both discharge into reservoir 4 so that the blood in the reservoir may be batch treated cyclically for a predetermined length of time. See page 4 lines 4-22 of Wratten.

Applicants respectfully submit that Wratten does not show or teach "[A] hemofiltration system to treat an inflammatory mediator related disease in a mammal **including selectively combining a post adsorption ultrafiltrate steam with a filtered blood stream** . . ." as further defined in Amended Claim 1. Wratten does not show or teach various features of Applicants' invention such as, but not limited to, ". . . tubing operably attached to the hemofilter for use in **selectively** combining the post absorption ultrafiltrate stream with the filtered blood stream and the tubing returning the combined stream to the mammal" as further defined in Amended Claim 1.

Claims 2 and 5 are dependent from Claim 1. Since Claim 1 as amended is now deemed allowable, Claims 2 and 5 are allowable.

Applicants request withdrawal of all rejections and allowance of Claims 1, 2 and 5 as amended.

Rejections under 35 U.S.C. §103

Claims 3 and 4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wratten. Applicants respectfully traverse and submit that Wratten does not render Claims 3 and 4 obvious.

Since Claim 1 as amended is now deemed allowable, Claim 3 and 4 are allowable. Applicants request withdrawal of all rejections and allowance of Claims 3 and 4.

Claims 6-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wratten in view of U.S. Patent No. 5,846,419 issued to Bernd Nederlof ("Nederlof"). Applicants respectfully traverse and submit the cited art combinations, even if proper, which Applicants do not concede and expressly traverse, does not render the claimed embodiment of their invention obvious.

In order to establish a prima facie case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580

(C.C.P.A. 1974). Furthermore, according to § 2143 of the Manual of Patent Examining Procedure, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Wratten expressly teaches that the most commonly used systems for purifying blood or plasma of toxins are absorbing the toxins on solid media (hemoperfusion and plasmaperfusion) or ultrafiltering the blood or plasma through an appropriate semipermeable membrane. Wratten further expressly teaches two methods or techniques for ultrafiltering blood or plasma using a semipermeable membrane — convection and diffusion. See for example Wratten page 2 lines 13-34:

CONVECTION which purifies blood or plasma with the aid of a transmembrane pressure (TMP) or a pressure gradient through an associated membrane (hemofiltration or plasmafiltration). The TMP typically causes fluid to move in bulk across the associated membrane and carries with the bulk fluid solute molecules to be removed; and

DIFFUSION which purifies blood or plasma by bringing the blood or plasma to be purified into contact with one side of an associated membrane and bringing an appropriately formulated wash solution or dialyzate into contact with an opposite side of the associated membrane. The solute molecules to be removed move down a concentration gradient from the blood or plasma on the one side of the associated membrane into the dialysate on the opposite side of the associated membrane.

Ultrafiltration or membrane separation of blood using **CONVECTION** may sometimes by referred to as "hemofiltration" or "plasmafiltration". Ultrafiltration or membrane separation of blood using **DIFFUSION** may sometimes be referred to as "hemodialysis" or "dialysis".

Applicants respectfully submit that ultrafiltering or membrane separation of blood or plasma by either "convection" or by "diffusion" are substantially different techniques due to their different mechanisms of moving solute molecules. For example, "diffusion" generally

requires the use of an associated dialyzate fluid. Solute molecules to be removed move down their concentration gradients from the blood or plasma into the dialysate. The dialysate is the source of the concentration gradient. TMP is not the driving force in diffusion. Dialysis is a more complex procedure typically requiring abundant amounts of relatively expensive dialysis fluid. "Convection" does not generally require the use of a dialyzate. Convection using a conventional hemofiltration system relies on TMP to drive a bulk flow of fluid across the membrane. The bulk flow of fluid carries or "drags" solute molecules with the fluid. No concentration gradient is involved and no dialysate is needed. Each procedure has its respective significant advantages and disadvantages. They are not interchangeable for many applications.

Wratten teaches that hemodyalisis particularly if combined with one or more of the methods discussed in Wratten is the most effective but is relatively lengthy in terms of purification time and therefore fails to provide sufficient toxin removal in acute cases. Wratten clearly teaches away from the use of dialysis type equipment to treat an inflammatory mediator related disease such as sepsis, septic shock or SIRS/MODS/MOSF in a mammal. See Wratten page 2 lines 25-34.

Nederlof teaches apparatus which includes the use of dialyzer 12 and dialyzer fluid path 20. See Nederlof column 3, lines 30-67. Wratten clearly teaches away from the use of a dialyzer to treat inflammatory mediator related diseases.

Applicants respectfully traverse the Examiner's comments concerning the teachings of Nederlof and particularly with respect to Figure 2 of Nederlof. For example, Nederlof expressly teaches that for embodiments such as shown in Figures 1 and 2 that dialyzer 12 may be used to purify blood flowing through blood supply line 82 to first chamber 16 of dialyzer 12. Membrane 18 divides dialyzer 12 into first chamber 14 and second chamber 16. Dialyzer fluid flows into first chamber 14 of dialyzer 12 and exits through discharge line 24.

Nederlof further teaches in column 4, lines 37-44 that one of the benefits of his invention includes shut off device 71 which allows shutting off supply line 70 which directs dialysate to first chamber 14. Nederlof further says "during hemofiltration, then, a hemofilter is preferably used in place of a dialyzer 11." See column 14, lines 44-45. Applicants respectfully submit that the reference to a dialyzer 11 should be dialyzer 12. Nederlof expressly teaches that dialysate may be directed through membrane 62 of second sterile filter 60 for purposes of flushing membrane 40 of first sterile filter 38.

Nederlof teaches dialyzer fluid source (26) that provides dialyzer fluid to a first sterile filter (30) and a second sterile filter (60) for sterilizing of the dialysate solution. The receiving chambers of both (42 and 64 respectively) are configured to be flushed periodically to remove accumulated bacteria. In the second sterile filter: "...the inventive arrangement of a second sterile filter the dialyzer fluid which is shunted off as a substituate solution is subjected to a second, sterilizing filtration action to thereby effectively prevent contamination of the substituate solution should any leak occur in the membrane of the first sterile filter." (C2, lines 34-39). The substituate solution flows through substituate line 72 driven by substituate pump 76 to the drip chamber. In summary, Nederlof teaches taking dialyzer fluid from a source and sterilizing the dialyzer fluid for two purposes: first, for use as dialyzer fluid, second, for use a substituate fluid **when dialyzer 12 of Nederlof has been replaced by a hemofilter**. Substituate fluid may be more generally known as a replacement fluid.

Nederlof and particularly Figure 2 of Nederlof does not show or teach an adsorptive device operable to create a post adsorption ultrafiltrate stream as further defined in Amended Claim 6. Nederlof and particularly Figure 2 of Nederlof does not show or teach combining filtered blood with the post absorption ultrafiltrate stream as further defined in Amended Claim 6. Nederlof teaches a dialysis system in which the dialysate fluid is normally maintained separate from and isolated from the blood. In Figures 1 and 2, Nederlof shows dialysate discharged at 90 and purified blood discharged at 85. Nederlof expressly teaches that purified dialysate may be combined in drip chamber 78 with filtered blood. See FIGURE 2 of Nederlof.

Claim 6 has been further amended to define various features of Applicant's invention including, but not limited to, ". . . a hemofilter operable to remove an ultrafiltrate comprising a fraction of plasma water, electrolytes, peptides and small proteins including inflammatory mediators from a bloodstream extracted from the mammal and to create a filtered bloodstream and an ultrafiltrate stream comprising the fraction of plasma water, electrolytes, peptides and small proteins including the inflammatory mediators . . . an adsorptive device containing at least one absorbent material operable to receive the ultrafiltrate stream from the hemofilter . . . means for selectively combining the post-adsorption ultrafiltrate stream with the filtered bloodstream and returning the combined stream to the mammal."

Nederlof teaches that all spent dialysate and/or ultrafiltrate is discarded. Nederlof does not show or teach " . . . means for selectively combining the post adsorption ultrafiltrate

with the filtered blood stream and returning the combined stream to the mammal" as further defined in Amended Claim 6. Applicants respectfully submit that neither Wratten and/or Nederlof, separately or in combination, show or teach a hemofiltration system as further defined in Amended Claim 6. Applicants respectfully submit that there is no teaching and no basis to combine Nederlof with Wratten and even if combined, the combination would not result in Applicants embodiment as defined in Amended Claim 6.

Claim 6 as amended is now deemed allowable.

Claims 7, 8, 9 and 10 are dependent from Claim 6. Since Claim 6 as amended is now deemed allowable, Claims 7, 8, 9 and 10 are allowable.

Applicants request withdrawal of all rejections and allowance of Claims 6-10 as amended.

Claim 11 as amended calls for various features of Applicant's invention, including, but not limited to, " . . . a hemofilter operable to remove an ultrafiltrate with inflammatory mediators from a bloodstream extracted from the mammal and to create a filtered bloodstream and an ultrafiltrate stream with the inflammatory mediators . . . an adsorptive device containing at least one adsorbent material operable to receive the ultrafiltrate stream from the hemofilter and to remove a wide range of the inflammatory mediators therefrom to create a post-adsorption ultrafiltrate stream without the inflammatory mediators removed by the at least one adsorbent material . . . tubing operable to combine the post adsorption ultrafiltrate stream without the inflammatory mediators removed by the at least one adsorbent material with the filtered bloodstream . . . a first pump to transfer the post adsorption ultrafiltrate from the adsorptive device . . . a second pump to transfer a portion of the post adsorption ultrafiltrate which is not returned to the mammal to a waste reservoir."

Applicants respectfully submit that neither Wratten and/or Nederlof show or teach various features of Applicants' invention as further defined in Amended Claim 11.

Claims 12, 13, 14 and 15 are dependent from Claim 11. Since Claim 11 as amended is now deemed allowable, Claims 12, 13, 14 and 15 are allowable.

Applicants request withdrawal of all rejections and allowance of Claims 11-15 as amended.

Information Disclosure Statements

Applicants would like to bring to the Examiner's attention that the Examiner made no indication that Reference "P" submitted with Information Disclosure Statement and PTO Form 1449 filed on October 26, 2006 had been considered in the Office Action mailed July 13, 2007. Applicants respectfully request confirmation of the consideration of Reference "P". Applicants attach a copy of the PTO Form 1449 that was attached to the Office Action mailed July 13, 2007 and respectfully request that the Examiner place his initials next to Reference "P" if citation is to be considered or draw a line through the citation if the citation is not to be considered.

Applicants would like to bring to the Examiner's attention that Applicants filed an Information Disclosure Statement and PTO Form 1449 for the Examiner's review and consideration on October 5, 2007. Applicants respectfully request that Examiner review this IDS and PTO Form 1449.

Petition For Extension Of Time

Applicants request that the Commissioner charge the filing fee of $230.00 for the Petition for Two-Month Extension of Time to Deposit Account No. 50-2148 of Baker Botts L.L.P. and to charge any additional fees or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

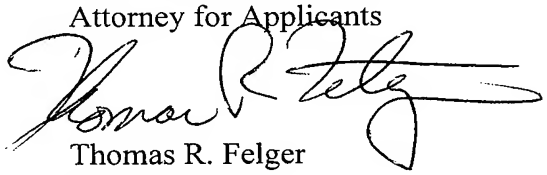
CONCLUSION

Applicants have made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicants respectfully request reconsideration of the pending claims as amended and new Claims 16 and 17.

Applicants authorize the Commissioner to charge $65.00 for the statutory disclaimer fee, charge $105.00 for the one extra new independent claim and $230.00 for the Petition for a Two-Month Extension of Time to Deposit Account No. 50-2148 of Baker Botts L.L.P. Applicants believe there are no additional fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicants' attorney at 512.322.2599.

Respectfully submitted,
BAKER BOTTS L.L.P.
Attorney for Applicants



Thomas R. Felger
Reg. No. 28,842

Date: 13 DEC 2007

SEND CORRESPONDENCE TO:
BAKER BOTTS L.L.P.
CUSTOMER NO. **31625**
512.322.2599
512.322.8383 (fax)

Enclosures:
1) Copy of IDS and PTO Form 1449 filed on October 26, 2006 and copy of Electronic Acknowledgment Receipt.
2) Fee Transmittal and executed Terminal Disclaimer and Statement of Assignee

PTO-1449	Application No.	Applicant(s)		
Information Disclosure Citation in an Application	10/826,736	James R. Matson et al.		
	Docket Number	Group Art Unit	Filing Date	
	067062.0129	3762	April 16, 2004	

U.S. PATENT DOCUMENTS

		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
/LD/	A	4180460	12/25/79	Calari	210	182	12/11/78
/LD/	B	4355906	10/26/82	Ono	366	274	4/3/81
/LD/	C	4596779	6/24/86	Ono	435	286	3/23/83
/LD/	D	4781068	11/1/88	Pradelli	73	861.38	4/17/87
/LD/	E	5044901	9/3/91	Fumero et al.	417	474	8/27/90
	F						
	G						
	H						
	I						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	J							
	K							
	L							
	M							
	N							
	O							

NON-PATENT DOCUMENTS

		DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
→	P	Rinaldo Bellomo et al., Nomenclature for Continuous Renal Replacement Therapy Atlas of Hemofiltration, p. 11-14	2002
	Q		
	R		
	S		
	T		
	U		
	V		

EXAMINER	/Leslie Deak/	DATE CONSIDERED	07/05/2007

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Electronic Acknowledgement Receipt

EFS ID:	1275266
Application Number:	10826736
International Application Number:	
Confirmation Number:	1355
Title of Invention:	Hemofiltration systems, methods and devices used to treat inflammatory mediator related disease
First Named Inventor/Applicant Name:	James R. Matson
Customer Number:	31625
Filer:	Michelle Lecointe/Adesewa Faleti
Filer Authorized By:	Michelle Lecointe
Attorney Docket Number:	067062.0129
Receipt Date:	26-OCT-2006
Filing Date:	16-APR-2004
Time Stamp:	12:25:08
Application Type:	Utility

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed	IDSandPTO0129.pdf	84501	no	3
Warnings:					

Information:					
This is not an USPTO supplied IDS fillable form					
2	NPL Documents	NomenclatureforContinuous Renal.pdf	263486	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	347987	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.